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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,299	01/05/2000	John L. Schenk	22091-701	1509

7590 02/09/2006

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EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/478,299

Applicant(s)

SCHENK, JOHN L.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005 and 20 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-65 and 67 is/are pending in the application.
- 4a) Of the above claim(s) 40,41,55,56,60-62,65 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,39,42-54,57-59,63 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

The election/restriction of record is maintained for the reasons of record.

Claims 40, 41, 55, 56, 60-62, 65, 67 remain withdrawn from further consideration as being drawn to non-elected subject matter.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 38, 39, 42-54, 57-59, 63, 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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There is still no support in the specification for the ranges of sperm cells claimed. There is no support for limitations such as, "to at least about 5 million per milliliter to at least about 10 million per milliliter of extender", "equine sperm cells between about 1,000,000 and about 25,000,000".

The specification may mention specific points of the concentration of sperm cells (i.e. 5×10^6) but it does not provide for the claimed range of the concentrations (i.e. between about 1,000,000 and about 25,000,000). The concentrations in table 1 are noted but they are only isolated concentrations, there is no support for ranges of these concentrations, only the specific points tested. The specification is also noted by applicant on page 11, lines 25-28 as teaching concentration ranges from 1 million-300 million, 10 million to 50 million, and 10 million to 20 million, but not the ranges applicant has claimed. Thus, the claims need to be amended to the ranges for which they find support for in the instant specification.

The time limitation in claim 64 still has no support. In fact, as applicant noted, they have support for 1-18 hours and between about 3 and about 6 hours but not support for "not greater than 6 hours".

Claims 38, 39, 42-54, 57-59, 63, 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Further, what is meant by , "to at least about 5 million per milliliter to at least about 10 million per milliliter of extender" ? Is this the concentration of the extender before it is applied to the sperm cells ? Is the 5 million referring to the number of sperm cells. So how much extender is added to each sperm cell ?

This was never addressed by applicant.

Cooling is still not clear in claim 38. Cooling to what temperature ? Cooler than what ?

Claims 63 and 64 are confusing. What step is this referring to ? What steps does this step occur between ? It might be clearer if applicant refers to the steps by the letters they correlate from in claim 38, i.e. step b. What temperature is cooler ? Cooler than what ? This is relative and subjective. There is no point of reference for one to compare it to.

Claim Rejections - 35 USC § 103

Claims 38, 39, 42-54, 57-59, 63, 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salisbury et al. in view of Spaulding and Shrimpton.

The claims still are obvious over the cited prior art of record. Applicant's limitation in claim 38 of "sorting said sperm cells, without the presence of protective compounds in seminal plasma" is met since as applicant notes on page 10 of their response filed 2/28/2005, that flow cytometry which is used by Spaulding has been shown to work and is now in practice as applicant has also done. Applicant states on page 10 that sorting

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without the presence of protective compounds is a feature that occurs when flow cytometry is used to achieve sex sorting which Spaulding has also done just like applicant and this is of record. Thus, the references meet the claim limitations.

Applicant also argues that the concentrations of the sperm cells in the extenders is 5 million to 10 million and applicant has pointed to table 1 of the specification to support this, but these points go up and down. For example, the values go up as one approaches 10 million and then decreases as one goes above 10 million. Also, it is not clear what this signifies. It is not clear what significance the increase in the numbers means. Does this increase anything ? Just because one yields higher numbers at 10 million this does not correlate to anything and if it does what does it correlate to ? Further, it is not clear what the 61 refers to in relation to 10 million in table 1. Also it is noted that the values at 24 hours and 48 hours differ in some way. It is not clear what this signifies.

Applicant has submitted a declaration by John Schenk filed 1/20/2006. While Mr. Schneck's declaration is noted what is not clear is how he can summarily dismiss the findings and teachings in a US Patent. Mr. Schenck argues that he has never observed a successful accomplishment of the techniques described in the Spaulding reference. While this may be true, it does not take away from the findings and teachings of Spaulding. Flow cytometry was well known in the art at the time this invention was made to sort sperm cells based on the DNA content of the sperm cell. For Mr. Schneck to say that he has seen no accomplishment of the Spaulding reference is only his opinion and does not meaning that Spaulding is inoperable as a reference. Further, the

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declaration argues that the concentrations of the sperm in the extender being from about "at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender" is not well taken since applicant does not have the data in his own specification to back that allegation up. As noted above, applicant only has support in the specification for either 10 million to 20 million sperm per milliliter or isolated points in table 1, 1.25 million sperm, 2.5 million sperm, 5 million sperm, 10 million sperm, 15 million sperm, and 20 million sperm. Nowhere in the specification or the original claims does applicant have support for the claimed "at least about 5 million per milliliter of extender to at least about 10 million per milliliter of extender". Without such evidence of support for the allegations in the declaration can it be given any weight or merit.

Applicant has further argued that in Spaulding the sperm are stripped of their natural protective compounds and are thus, as applicant concludes, subjected to a more stressful environment. Applicant states on page 10 of their response filed 2/2/8/2005 that sorting without the presence of protective compounds is a feature that occurs when flow cytometry is used to achieve sex sorting which Spaulding has also done just like applicant and this is of record. Thus, this argument is simply moot.

This is a RCE of applicant's earlier Application No. 09/478,299. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had

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been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in dark ink, appearing to read 'M. Meller', followed by a long horizontal line extending to the right.

Michael V. Meller
Primary Examiner
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MVM